

## **REMARKS**

The specification of the instant application has been amended to include a Sequence Listing in paper and computer readable form pursuant to 37 C.F.R. § 1.821(c) and (e). Pursuant to 37 C.F.R. § 1.821 (f) and (g), the written and the computer readable forms of the Sequence Listing are identical and do not include new matter or go beyond the disclosure of the application as filed.

Claims 1-5, 8-10, 12-16, 24-46, and 53-59 were pending in the instant application. Claims 1-5 are withdrawn from consideration. By this amendment, Claims 8 and 56 are amended to recite that the inflammatory disease is stroke, support for which may be found in the specification of the application as filed at, *e.g.*, ¶¶ 0046-0047, and Claims 8, 12, 24-31, 33, 34, 36-38, 40, 41, 53-55, 57, and 59 are amended to more clearly define the invention. Claims 1-5, 13-16, and 43-46 are canceled without prejudice. Applicants reserve the right to pursue the subject matter removed by the present amendments to and cancellation of the claims in this or one or more related applications. By this amendment, new Claim 60 is added, support for which may be found in antecedent Claim 58. Thus, no new matter is added with this amendment. By this amendment, Claims 8-10, 12, 24-42, and 53-60 are pending.

### **A. Information Disclosure Statement**

Applicants acknowledge with appreciation the Examiner's consideration of the information disclosure statement submitted on December 18, 2009.

### **B. Withdrawn Claim Objection/Rejections**

Applicants acknowledge with appreciation the withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, the withdrawal of the rejections under 35 U.S.C. § 112, second paragraph for indefiniteness, and the withdrawal of the rejection under 35 U.S.C. § 103(a).

**C. The New Rejections Under 35 U.S.C. § 112, Second Paragraph Should Be Withdrawn**

Claims 8-10, 12-16, 24-46, and 54-59 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly failing to set forth the subject matter which applicants regard as their invention. In particular, it is alleged on page 5 of the Office Action that since the amended sequence listing, which adds the sequence identified as SEQ ID NO:5, was submitted in an Amendment, filed April 14, 2009, that was non-responsive to the previous Office Action, the sequence listing was not entered. Page 5 of the Office Action requires that if Applicant desires to incorporate SEQ ID NO:5 as essential material, the sequence listing must be resubmitted in order to be considered and entered.

In response, Applicants resubmit herewith a Substitute Sequence Listing in paper and computer readable form. The Substitute Sequence Listing introduces SEQ ID NO:5. SEQ ID NO:5 represents the amino acid sequence of erythropoietin. The amino acid sequence of erythropoietin was well-established in the art. See, *e.g.*, ¶ 0005 of the present specification. In particular, U.S. Patent 4,703,008 (cited in the present application at ¶ 0005, line 6 and attached as Exhibit A to Applicants' response of March 24, 2009) discloses the amino acid sequence of erythropoietin (see Figure 6 of U.S. Patent 4,703,008). U.S. Patent No. 4,703,008 is incorporated by reference in the specification of the application as filed (see ¶ 00325).

In view of the resubmission of the Substitute Sequence Listing, the claim rejections under 35 U.S.C. § 112, second paragraph, are overcome and Applicants respectfully request their withdrawal.

**D. The Obviousness-Type Double Patenting Rejections Should Be Withdrawn**

In the Office Action, the rejection of Claims 8-10, 12-16, 25, 43, 54, and 55 on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-16 of U.S. Patent No. 6,531,121 was maintained on the grounds that the Terminal Disclaimer filed on December 18, 2009 was disapproved.

The rejection of Claims 8, 15, 16, 28-31, 33, 34, 36, 39, 53, and 54 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1,

14, 16-21, 25, 28, 29, 61, 62, and 63 of allowed Application No. 10/185,841, now U.S. Patent No. 7,767,643 (reference A107 of the Information Disclosure Statement submitted concurrently herewith), in view of Brines *et al.*, 2000, PNAS USA 97:10526-10531, was maintained on the grounds that the Terminal Disclaimer filed on December 18, 2009 was disapproved.

The provisional rejection of Claims 8, 13-16, 31, 32, and 43 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 35, 37, 38, and 50-60 of copending Application No. 10/188,905 was maintained on the grounds that the Terminal Disclaimer filed on December 18, 2009 was disapproved.

Claim 56 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 10 and 14 of copending Application No. 11/880,275.

In response to the foregoing nonstatutory obviousness-type double patenting rejections as they apply to the pending claims, without agreeing to the merits of the rejections, and solely to expedite allowance of the claims, Applicants submit herewith a Terminal Disclaimer Under 37 C.F.R. § 1.321(c) ("Terminal Disclaimer") executed on behalf of The Kenneth S. Warren Institute, Inc., the Assignee of the above-identified application. Applicants respectfully assert that the submission of the Terminal Disclaimer overcomes the foregoing rejections under the judicially created doctrine of obviousness-type double patenting, and respectfully request their withdrawal. Applicants note that Claims 13-16 and 43 are canceled without prejudice.

Claims 8 and 56 were rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 39 and 41 of copending allowed Application No. 10/573,905. Claims 39 and 41 of Application No. 10/573,905 have issued as claims 1 and 2 of U.S. Patent No. 7,645,733 (the "'733 patent"; reference A105 of the Information Disclosure Statement submitted concurrently herewith). It is alleged on page 5 of the Office Action that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or overlapping subject matter. In particular, the Examiner asserts that adhesion formation, in issued claims 1 and 2 of the '733 patent, is directly or indirectly related to an inflammatory pathology. With this amendment,

instant Claims 8 and 56 have been amended to require that the inflammatory disease is stroke. Thus, Claims 8 and 56 are patentably distinct from claims 1 and 2 of the '733 patent, and accordingly Applicants respectfully request the withdrawal of their rejection for nonstatutory obviousness-type double patenting.

Claims 8 and 56 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 27 of copending Application No. 11/631,458. In view of the abandonment of Application No. 11/631,458 as of October 21, 2009 for failure to respond to the Office letter dated September 21, 2009, this rejection is moot and Applicants respectfully request its withdrawal.

Claim 56 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 10 and 11 of copending Application No. 11/881,759. In view of the abandonment of Application No. 11/881,759 as of March 21, 2010 for failure to respond to a Notice of Appeal filed January 21, 2010, this rejection is moot and Applicants respectfully request its withdrawal.

### **CONCLUSION**

Applicants respectfully request entry of the amendments and remarks made herein into the file of the instant application. Applicants estimate that the amendments and remarks made herein place the application in condition for allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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/Eileen E. Falvey/

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Enclosures